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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/324,343
Filing Date: June 02, 1999
Appellant(s): GEERKE ET AL.

Joseph Lucci
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 11/19/2007 appealing from the Office action mailed 1/17/2007.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings, which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

No amendment after final has been filed.

(5) Summary of Claimed Subject Matter

The summary of the claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

The following is a listing of the evidence (e.g., patents, publications, Official Notice, and admitted prior art) relied upon in the rejection of claims under appeal.

Barclay et al. (US Patent 5,248,310)

Wong et al. (US Patent 5,785,994)

Riddle et al. (US Patent 5,294,770)

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in Graham vs John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. Claims 18-20, 32-33, 35-36, 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barclay et al. (US Patent 5,248,310) in view of Wong et al. (US Patent 5,785,994) and Riddle et al. (US Patent 5,294,770).

2. The instant claims are directed to three-layer tablets comprising a first and second layer that contains a drug and at least one colorant, and a third layer containing a second and different colorant. The dependent claim further adds a coating layer to said tablets and methylphenidate chloride as the active ingredient.

3. Barclay teaches osmotic tablets comprising separate drug polymer and polymer layers wherein each layer is distinguishable from each other by a different color. Barclay specifically teaches the use of colorant to allow appropriate color contrast between layers of his formulation (see abstract, col 20, lines 26-60; col 7, lines 59-col 8, line 34). Barclay shows that coloring agents are used in the art for determining the formulation orientation. (see col 17, lines 20-56). At col 17, lines 20-55, Barclay describe an osmotic tablet comprising a white color drug containing layer and a reddish brown hydrophilic polymer layer. Barclay teaches the non-drug polymer layer to contain a reddish-brown color (see col 17, lines 40-44). Barclay describes the use of ferric oxide colorant as the colorant of choice. Barclay then compresses the drug and non-drug layer together and coats the resultant solid osmotic tablet with a translucent coating. (see col 17, lines 39-51).

Barclay coats the tablet with a translucent coating and describes that the drug/beneficial agent layer is detectable through such translucent coating (col 5, lines 42-51). Since color difference is easily detectable by naked eye, Barclay's tablet

inherently possesses capability to be detected by a colorant detector. In fact, Barclay detects or observes the white drug-containing layer from the reddish-brown polymer-layer in the tablet. (see col 17, lines 52-54). After detecting which side of the tablet contains the drug layer (in another words, detecting the orientation of the tablet), Barclay chooses to drill a passage whole through the drug-containing layer for delivering the drug from the osmotic tablet (see cool 17, lines 55-57). Therefore, Barclay teaches the use of colorant for purposes of detecting orientation of a two layered osmotic tablet.

Barclay also teaches suitable size or shape for his tablets to allow comfortable oral delivery (see col 6, lines 20-24, figures 1-3). Such suitable shapes include capsule-shaped tablets as depicted in figure 1-3 of Barclay's Patent. Barclay also teaches the use of methylphenidate hydrochloride as a suitable drug in his formulation. (see col 11, lines 13-15). Barclay does not teach a three layer osmotic tablet.

Barclay only fails to explicitly teach a three-layered tablet and further use a color detector to orient the tablet formulations. However, preparing a two or three layer osmotic tablet and using a color detector to orient a tablet are well within the level of an ordinary skill in the art.

4. Wong and Riddle are respectively used to show the general knowledge in the art to make a three layer tablet or use a color detector to orient tablet formulations during their manufacturing process.

5. Wong teaches a three layer osmotic tablet using the same drugs, same polymeric moieties and same drilling technique as Barclay. Wong teaches a three or

more layered tablet that provides a varying pattern of drug release (see abstract, col 2, lines 4-20). Such pattern is achieved by drug concentrations in each layer of Wong's formulation. Wong et al. disclose that their tablets are prepared by pressing the three layers to form a solid core (see col 19 lines 10-18). Wong also describes methylphenidate as a suitable drug in his formulation (col 10, line 21).

6. Wong teaches three-layered osmotic tablets containing a port (see abstract). At least one layer of Wong's tablets contains a dye such as ferric oxide. Wong discloses tablet dosage forms comprising three layers wherein first layer is drug free and is a push layer which contains a colorant such as ferric oxide (see col 17 line 23; col 20, lines 20-25) and the third layer comprise a colorant (see figure 3, col 16 lines 58-67, col 18 lines 1-42). Thus, adding additional drug layers is well within the scope of Wong's teachings.

The tablet of Wong comprises an exit port (see col 17 line 56) meeting the limitation of claims 25, 30 (see col 15 lines 15-18). Wong et al disclose that their tablets are prepared by pressing the three layers to form a solid core (see col 19 lines 10-18). Wong also describes methylpheidate as a suitable drug in his formulation (col 10, line 21). Wong essentially teaches the same tablets as Barclay. Except that Wong is a three or more layered tablet that provides a varying pattern of drug release. (see abstract, col 2, lines 4-20). Such pattern is achieved by drug concentrations in each layer of Wong's formulation.

7. Barclay and Wong are within the same field of endeavor and therefore their teachings are combinable. Barclay employs aspirin, steroids, methylphenidate, etc...

(see col 11, lines 1-65, examples 1, 3 and 5). Wong also employs the same drugs (see Wong at col 10-col 11, lines 7-8).

Barclay describes hydrophilic polymers and hydrogels as suitable polymeric units (see col 13, lines 23-67). Wong also teaches the same polymeric moieties (see Wong at col 12, lines 44-col 13, line, 65).

Barclay teaches osmagents such as magnesium sulfate etc. (see col 13, lines 4-20). Wong teaches the use of the same osmagents (see col 5, lines 33-50).

Barclay uses the ferric oxide as the colorant in the polymeric layer (see example 2). Wong also uses ferric oxide as a colorant in his polymeric layer (col 17, lines 18-26).

The only difference between Barclay and Wong is that Barclay teaches a two layer osmotic tablet, but Wong teaches a three layer osmotic tablet. Nevertheless, their combined teachings do not explicitly teach the use of a color detector during their manufacturing process.

8. Riddle is used to show that using a color detector is a well recognized practice in the art of orienting tablet formulations during their manufacturing process. (see abstract, fig 1B, col 5). Riddle explicitly states that the orientation of tablets is recognized typically by their color differences on the side of tablets (see col 7, lines 10-60; specifically col 7, line 30-31). Riddle further states that his detector can be used in any tablet treatment process, which can include the step of creating a delivery port (see col 1-2; col 7, line 35-col 8, line 32). Thus using a color detector in the art has been practice at least since 1992.

9. Therefore, it would have been obvious to one ordinary skilled in the art at the time of invention to employ Barclay's method of detecting different layers in the three layer osmotic dosage forms of Wong, by incorporating a coloring agent, as shown by Barclay, in any desired layer, because the ordinary skill in the art would have had a reasonable expectation of success to use different colorants to facilitate ease of detection of each formulation layer and even further employ a color detector such as those described by Riddle to differentiate the orientation of the tablets during their manufacturing process for any suitable step such as creating a delivery port.

(10) Response to Argument

Appellant argues that the cited references do not disclose a tablet having a drug/drug/no drug orientation three-layer tablet structure. Specifically, the Barclay patent does not disclose a dual drug orientation. The proposed combination of Wong and Barclay patents would yield a different structure, having a no drug/drug/no drug orientation.

This is not persuasive because Appellant has misinterpreted the references. The combination of the cited references does indeed form a drug/drug/no drug orientation three-layer tablet structure. Barclay clearly discloses a tablet with a drug layer and no drug layer. Barclay only fails to explicitly teach a three-layered tablet. However, preparing a two or three layer osmotic tablet is well within the level of an ordinary skill in the art.

Wong and Riddle are respectively used to show the general knowledge in the art to make a three layer tablet or use a color detector to orient tablet formulations during

their manufacturing process. Wong teaches a three layer osmotic tablet using the same drugs, same polymeric moieties and same drilling technique as Barclay. Wong teaches a three or more layered tablet that provides a varying pattern of drug release. Such pattern is achieved by drug concentrations in each layer of Wong's formulation.

Therefore, it would have been obvious to one ordinary skilled in the art at the time of invention to employ Barclay's method of detecting different layers in the three layer osmotic dosage forms of Wong, by incorporating a coloring agent, as shown by Barclay, in any desired layer, because the ordinary skill in the art would have had a reasonable expectation of success to use different colorants to facilitate ease of detection of each formulation layer and even further employ a color detector such as those described by Riddle to differentiate the orientation of the tablets during their manufacturing process for any suitable step such as creating a delivery port.

Appellant argues that one of the structures (element 14 in Figure 2 and 4) in the Wong patent upon which Examiner relies as a three layer tablet is a drug containing overcoat. Because this overcoat does not correspond to any of the claimed layers (at least because it is not suitable to be compressed into a capsule-shaped osmotic tablet) there is no motivation to have produced the claimed invention.

This is not persuasive because Appellant has admitted to the fact that Wong teaches a three layer tablet as taught as element 14 in Figure 2 and 4. Examiner respectfully reminds Appellant that nothing in the Wong reference teaches that this particular composition comprising the overcoat cannot be compressed into a capsule-

shaped tablet. This is merely Appellant making a conjecture based on no factual evidence or teaching from the Wong reference.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Yong S. Chong, Ph.D.
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Art Unit 1617

ysc
January 30,2008

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